

Reply & Amendment to Final Office Action dated January 08, 2009 with RCE

REMARKS

In response to the Office Action mailed January 08, 2009, Applicants filed a Reply & Amendment After Final Rejection on February 23, 2009. By Advisory Action mailed March 13, 2009, the Examiner stated that the amendments presented in the Reply & Amendment After Final raised new issues and would not be entered.

By way of this Reply & Amendment, Applicants have repeated the prior claim amendments, and respectfully request that they be entered at the present time. A Request for Continued Examination (RCE) is being filed concurrently. Reconsideration of the application in view of the amendments and following remarks is respectfully requested.

Claims 11 and 15-21 are pending in the subject application. Claim 11 is independent and claims 15-21 depend, directly or indirectly, from claim 11. As set forth above, claim 11 is amended. Claim 11 has been amended to enhance the clarity of the subject matter as claimed. Support for the amendment is found, for example, at page 47, lines 5-15 and pages 97-98 of the specification. No new matter has been introduced by the amendment. Amended claim 11 and claims 15-21 are pending in the subject application.

In the Office Action dated January 08, 2009, claims 11 and 15-21 were rejected under 35 U.S.C. § 101 as lacking utility. The Examiner believed that the claims as recited prior to the present amendment did not clearly reflect an obvious benefit of the method. This rejection is respectfully traversed.

As set forth above, amended claim 11 (and thus claims 15-21 which depend therefrom) of the subject application is directed to an *in vitro* method for assessing the ability of particular compounds to inhibit VEGF production in a cell from a tumor of an individual patient in need of treatment. This is an *in vitro* method that utilizes tumor cells from patients that are in need of therapy and who are potential candidates for receiving *in vivo* a compound that inhibits VEGF production. A utility of the amended pending claims is to determine whether a particular tumor from an individual cancer patient is responsive to a specific compound *in vitro* in order to assess whether the patient is a candidate for receiving the compound *in vivo*. Applicants submit that amended claims 11 and 15-21 satisfy the utility requirement of Section 101.

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Therefore, Applicants believe that the rejection of claims 11 and 15-21 under 35 U.S.C. § 101 has been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

In the Office Action, claims 11 and 15-21 were rejected under 35 U.S.C. § 112, second paragraph, as failing to set forth the subject matter which Applicants regard as their invention. It was believed by the Examiner that the purpose of the invention was not set out in the claims. This rejection is respectfully traversed

As set forth above, claim 11 has been amended (and thus claims 15-21 which depend therefrom) to enhance the clarity of the claimed method.

Therefore, Applicants believe that the rejection of claims 11 and 15-21 under 35 U.S.C. § 112, second paragraph, has been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

In the Office Action, claims 11, 15, 16 and 18-20 were rejected under 35 U.S.C. § 103(a) as unpatentable over Srimanth et al. (Arzneim.-Forsch./Drug Res. 52, No. 5, 388-392, 2002). The rejection is respectfully traversed.

As set forth above, amended claim 11 (and thus claims 15-21 which depend therefrom) of the subject application recites in part: “An *in vitro* method for assessing the ability of a compound to inhibit VEGF production in a cell from a tumor of a patient in need of treatment ... said compound of the formula I ...” Step (b) of claim 11 requires determining whether VEGF production is inhibited by the compound. Accordingly, the pending claims require that the cell be from a tumor of a patient in need of treatment and that the compound of formula I be assessed for the inhibition of VEGF production.

A review of Srimanth et al. finds that the only description of the assay used to test for biological activity is the short section entitled “2.2 Pharmacology” at page 392. The results are stated therein to represent “the drug concentration (mol/l) producing 50% inhibition of cell growth.” There is no teaching or suggestion that the compounds tested by Srimanth et al. inhibit VEGF production. Based on the disclosure of Srimanth et al., one of ordinary skill in the art could not know whether the compounds tested therein would be useful to inhibit VEGF

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production. In addition, the disclosure of Srimanth et al. does not reveal whether the cell lines used therein were from a tumor of a patient in need of treatment.

Srimanth et al. is stated at page 2 of the Office Action to disclose the use of compounds 2a-2h to treat cancer. As noted above, the assay in Srimanth et al. was for inhibition of cell growth. (In addition, it is noted that the assay results presented in Srimanth et al. are in Table 2 which lists results for only compounds 2d and 2g, and not all of compounds 2a-2h.) There are thousands of journal articles that report the testing of compounds *in vitro* for ability to inhibit tumor cell growth. In the absence of knowledge of the disclosure of the subject application, why would one of skill in the art select the compounds of this one reference (Srimanth et al.) in order to assess for the ability to inhibit VEGF production? Applicants submit that, given there is no teaching or suggestion in Srimanth et al. that the compounds disclosed therein inhibit VEGF production, it is only when one of skill in the art is in possession of the teachings of the subject application that there is motivation to assess the compounds of Srimanth et al. for the ability to inhibit VEGF production. It would not have been obvious, within the meaning of Section 103, to one of skill in the art to test the compounds of Srimanth et al. for the ability to inhibit VEGF production. Applicants respectfully submit that the Patent Office has failed to establish a *prima facie* case for obviousness under Section 103.

Therefore, Applicants believe that the rejection of claims 11, 15, 16 and 18-20 under 35 U.S.C. § 103(a) over Srimanth et al. has been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.


Therefore, in light of the amendment and remarks set forth above, Applicants believe that all the Examiner's rejections have been overcome. Reconsideration and allowance of the pending claims (11 and 15-21) are respectfully requested. If there is any further matter requiring attention prior to allowance of the subject application, the Examiner is respectfully requested to contact the undersigned attorney (at 206-622-4900) to resolve the matter.

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The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to Deposit Account No. 031182.

Respectfully submitted,

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